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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO
666 THIRD AVENUE
NEW YORK, NY 10017

EXAMINER

KIM, YOUNG J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

10

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application N . | | Applicant(s) | |
| | 09/814,338 | | ROTHBERG ET AL. | |
| | Examiner | | Art Unit | |
| | Young J. Kim | | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70, 72 and 84-99 is/are pending in the application.
- 4a) Of the above claim(s) 1-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-70, 72 and 84-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action responds the Amendment received on May 19, 2003 (Paper No. 7).

Preliminary Remark

The Office acknowledges the cancellation of claim 71 and the addition of claims 88-99.

Election/Restrictions

This application contains claims 1-55 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The objection to the specification for outdated status of the parent application, made in the Office Action mailed on November 19, 2002 is withdrawn in view of the Amendment received on May 19, 2003, amending the specification to update the status of the parent application.

Art Unit: 1637

Claim Objections

The objection of claim 86 for depending on a subsequent claim, made in the Office Action mailed on November 19, 2002 is withdrawn in view of the Amendment received on May 19, 2003, amending the claim to its correct dependency.

Claim Rejections - 35 USC § 112 – Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56-68, 84, 85, 87, and 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 (and its dependents therefore) recites a conjunction after the first element of the substrate, rendering the claims indefinite in their metes and bounds with regard to what is included/excluded in/from the claimed substrate. Amending claim 56 to include “and” after the phrase, “three times the diameter of an individual optical fiber;” would overcome this rejection.

Claim 57 is indefinite for the recitation of the phrase, “wherein *the nucleic acid is an anchor primer*,” due the present amendment to claim 56. Specifically, the amendment to claim 56 requires that now a plurality of beads be immobilized to the substrate, rendering it confusing where the anchor primer is immobilized to.

Claims 67 and 68 are indefinite for the recitation of the phrase, “oligonucleotides are attached to the surface,” because the base claim 56 recites two types of surfaces (top and bottom), rendering the claim confusing.

Art Unit: 1637

Claim 84 is indefinite for the recitation of the phrase, "so nucleic acids disposed in the wells of the fiber optic wafer," because the wells are recited as being filled with a plurality of beads, rendering the claim confusing where the nucleic acids are disposed.

Claim 85 recites the limitation "said microparticle." There is insufficient antecedent basis for this limitation in the claim due to the present amendment to the base claim 84.

Claim 87 recites the limitation "said analyte." There is insufficient antecedent basis for this limitation in the claim due to the present amendment to the base claim 84.

Claim 90 recites the limitation "cavitated surface." There is insufficient antecedent basis for this limitation in the claim due to the present amendment to the base claim 84. For the purpose of prosecution, the limitation is assume to be "cavitated fiber optic wafer."

Claim Rejections - 35 USC § 102 – Withdrawn

The rejection of claims 56-58, 64-70, 72, and 84-87 under 35 U.S.C. 102(a) as being anticipated by Walt et al. (WO 98/50782, issued November 12, 1998, IDS ref# B15), made in the Office Action mailed on November 19, 2002 is withdrawn in view of the Amendment received on May 19, 2003, amending the claims to include additional limitation.

Claim Rejections - 35 USC § 102 - Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1637

The rejection of claims 73-78 under 35 U.S.C. 102(a) as being anticipated by Walt et al. (WO 98/50782, issued November 12, 1998, IDS ref# B15), made in the Office Action mailed on November 19, 2002 is maintained for the reasons of record.

Applicants' arguments received on May 19, 2003 have been fully considered but they are not found persuasive for the following reason.

The major thrust of the Applicants' argument is that Walt et al. reference does not teach the newly added limitation of a "wafer" with a thickness between 0.5 mm to 5.0 mm with the attachment of pyrosequencing reagents thereto (page 6, Response). Applicants are advised that claims 73-78 recite no such limitation and therefore, Applicants' argument is moot in view of the present disposition of the claims, rendering the claims rejected under the cited reference.

Claim Rejections - 35 USC § 103 – Withdrawn

The rejection of claims 56-70, 72, and 84-87 under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (WO 98/50782, issued November 12, 1998, IDS ref# B15) in light of Pantano et al. (Chemistry of Materials, 1996, vol. 8, no. 12, pages 2832-2835), made in the Office Action mailed on November 19, 2002 is withdrawn in view of the Amendment received on May 19, 2003, amending the claims to include additional limitation.

Claim Rejections - 35 USC § 103 – Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1637

The rejection of claims 79-83 under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (WO 98/50782, issued November 12, 1998, IDS ref# B15) in light of Pantano et al. (Chemistry of Materials, 1996, vol. 8, no. 12, pages 2832-2835), made in the Office Action mailed on November 19, 2002 is maintained for the reasons of record.

Applicants' arguments received on May 19, 2003 have been fully considered but they are not found persuasive for the following reason.

The major thrust of the Applicants' argument is that Walt et al. reference does not teach the newly added limitation of a "wafer" with a thickness between 0.5 mm to 5.0 mm with the attachment of pyrosequencing reagents thereto (page 6, Response). Applicants are advised that claims 79-83 recite no such limitation and therefore, Applicants' argument is moot in view of the present disposition of the claims, rendering the claims rejected under the cited reference.

Claim Rejections - 35 USC § 103 – New Ground, Necessitated by Amendment

The following rejection is a new ground of rejection, necessitated by Applicants' Amendment, introducing new limitations into the claims which have not been previously examined.

Claims 56-70, 72, and 84-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (US 2003/0027126 A1, published February 6, 2003, priority March 14, 1997).

Claims 56-68 and 88-93 are drawn to a substrate comprising a cavitated fiber optic wafer, wherein the cavitated fiber optic wafer is produced from a fused bundle of a plurality of individual optical fibers having a diameter between 3 and 100 μm , the cavitated fiber optic wafer comprising a depth of 0.5 mm to 5.0 mm. Some embodiments are drawn to the various distances

Art Unit: 1637

between anchoring primers/pads and densities. Claims 69, 70, 72, and 94-99 are drawn to an array comprising the above substrate. Claims 84-87 are drawn to a system comprising the array.

Walt et al. disclose a substrate/array/system which comprises a cavitated fiber optic wafer formed from a fused bundle of a plurality of individual optical fibers [0035-0039], each individual optical fiber having a diameter slightly greater than $3.7\text{ }\mu\text{m}$ [0094]. The microsphere is disclosed as having fixed thereon, nucleic acids [0048; claim limitation 87], wherein the fixation could occur via a coated linker [0065-0066; claim limitation 67, 90, 91, 96, and 97]. Varying degrees of density of the substrate is disclosed [0029; claim limitation 64-66, 69, 70, and 72]. Walt et al. disclose that the substrate could comprise secondary enzymes which would allow pyrosequencing (or pyrophosphate sequencing) [0190-0192], wherein the enzymes are disclosed luciferase and sulfurylase [0193; claim limitation 92, 93, 98, and 99]. Walt et al. disclose that it is customary that a fiber optic ends are polished [0092; claim limitation 88 and 94]. Finally, the system disclosed by Walt et al. comprise a detection means via CCD camera (Figure 4; [0087]; claim limitation 85 and 86).

Walt et al. do not explicitly disclose that the cavitated fiber optic wafer comprises a depth between 0.5 mm and 5.0 mm.

Walt et al. do not explicitly disclose that a polished end of a fiber optic wafer is optically linked to a second fiber optic fiber.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Walt et al. to arrive at the invention as claimed.

One of ordinary skill in the art, at the time the invention was made, would have been motivated to modify the teachings for the following reasons.

Art Unit: 1637

Although Applicants' have amended the claims to recite that the substrate now comprises a cavitated fiber optic wafer, the wafer is defined by the claim as a bundle of fiber optic strands having a front end and a distal end (as disclosed by Walt et al.) with the length of the bundle being 0.5 to 5.0 mm (Applicants' term this "depth"). This limitation is obvious in view of making obvious aesthetic design changes. MPEP 2144.04 states that:

"The court found matters relating to ornamentation only *which have no mechanical function cannot* be relied upon to patentably distinguish the claimed invention from the prior art." (*In re Seid*, 161 F.2d 229, 73 USPQ 431 (CCPA 1947)).

The instant situation is analogous to that which was described in the above case because the length of the fiber optic bundle does not materially affect the ability of the substrate to assay for ligand binding assays. This is further evident in Applicants' claim 95 which requires that the ends of the shortened fiber optic bundles (of the wafer) be attached to second optical fiber bundles to be able to transmit the data across to the imaging device. The net effect, therefore, requires a long bundle of fiber optic fibers attached to an imaging device, all of which is disclosed by Walt et al. Since the distance between the cavitated end and the distal end of the fiber optic fiber (i.e., depth) does not have any mechanical function, such limitation would not, "distinguish the claimed invention from the prior art." (*In re Seid*), rendering the invention as claimed obvious over Walt et al. reference. Even if *arguendo* that the shortened length of the fiber optic bundle allows portability of the claimed substrates, such portability is also held to be obvious absent new or unexpected results (See *In re Lindberg*, 194 F.2d. 732, 93 USPQ (CCPA 1952) & MPEP 2144.04 (V)).

Therefore, the invention as claimed is obvious over the cited reference.

Art Unit: 1637

Double Patenting - Maintained

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The provisional rejection of claims 56, 57, 64-67, 69, 70, 73, 74, 76, 77, 84, and 85 under 35 U.S.C. 101 as claiming the same invention as that of claims 33, 35, 41-44, 45, 46, 49-52, 59, and 60 of copending Application No. 09/664,197, made in the Office Action mailed on November 19, 2002 is maintained for the reasons of record.

Applicants' request to have the rejection held in abeyance has been considered, but the rejection is maintained because neither of the applications involved have been patented or abandoned.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 56-70, 72-87 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-46 and 48-62 of copending Application 09/664,197, made in the Office Action mailed on November 19, 2002 is maintained for the reasons of record.

Applicants' request to have the rejection held in abeyance has been considered, but the rejection is maintained because neither of the applications involved have been patented or abandoned.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348.

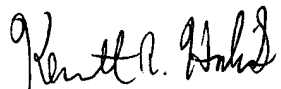
Art Unit: 1637

The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

8/7/03




KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/11/03